REMARKS

1. Support for The New Claims

The newly added claims find support throughout the original claims, specification and priority documents. Support for most of the limitations in the new claims can be found in the original claims. Below is a list of the new claims and where support for each new claim can be found.

New claims	Support[a]
147	9,18, 20, 22, 24, Claim 1 of U.S. Provisional Application No. 60/250,072[b]
148	Claim 1 of U.S.P.A. No. 60/250,072[b]
149	Claim 2 of U.S.P.A. No. 60/250,072[b]
150	8
151	9
152	8
153	9
154	10
155	19
156	23
157	21
158	14
159	15
160	16
161	17
162	11
163	12
164	13
165	25
166	26
167	p. 5, lines 14-16 of U.S.P.A. No. 60/250,072[b]
168	33
169	p. 9, lines 15-18
170	46
171	47
172	49
173	43, 44, 45
174	27
175	28
176	27

177	35
178	36
179	37
180	38
181	31
182	39
183	40
184	30
185	144, p. 18, line 33 to p. 19, line 11
186	146, p. p. 19, line 18 to p. 20, line 4
187	145
188	p. 1, lines 24 to 27

[a] Unless otherwise indicated, numbers refer to original claim number in this application No. 09/997126.
[b] The priority of U.S. Provisional Application No. 60/250,072 is claimed and it is incorporated by reference into this application

Applicants wish to direct the Examiner's attention to substantive differences between the new claims and the old claims.

Claim 147 is directed to atorvastatin hemi-calcium Form VIII. It is in Markush format wherein each member of the Markush group is a set of physical properties that identifies Form VIII. Member (b) of the Markush group is a set of peaks in the PXRD pattern of Form VIII that is characteristic of that form. The set is supported in original claim 9 of this application. The peak at 16.3 ° two-theta has been deleted because it is a weak peak and is not necessary to identify Form VIII.

Claim 167 is the broadest claim directed to a process for making Form VIII. It is broader than either of the three original independent claims that were directed to a process for making Form VIII (claims 27, 30 and 39). As indicated in the listing above, support for claim 167 can be found, *inter alia*, at p. 5, lines 14-16 of U.S. Provisional Application No. 60/250,072 from which this application claims priority and which is incorporated by reference on page 1, lines 6-9.

Claims 185 and 186, directed to a pharmaceutical composition and dosage form, respectively, differ from original claims 144 and 146 in that they expressly include at least one pharmaceutical excipient. Support for the inclusion of an excipient(s) in a pharmaceutical composition or dosage form can be found in the discussion spanning pp. 18-20 of the application.

Claim 188 directed to a method of reducing low density lipoprotein particle concentration in the bloodstream of a patient is supported, *inter alia*, on p. 1, lines 24-27.

2. **Applicants' Election and Traversal of The Restriction as to Groups IV, V, VIII, XXXI, XXXII And XXXIII**

Claims 147-166 correspond to the Examiner's Group II.

Claims 167-184 correspond to the Examiner's Groups IV, V and VIII. Claims 167-184 all depend either directly or indirectly from claim 147. Claim 167, from which claims 168-184 depend either directly or indirectly, better captures the unity of invention of Applicant's process for preparing atorvastatin hemi-calcium Form VIII as defined by claim 147 than do original claims 27, 30 and 39.

Claims 185 and 186 correspond to the Examiner's Groups XXXI and XXXIII.

Claim 187 corresponds to the Examiner's Group XXXII.

Applicants elect to pursue the invention of Group II, atorvastatin hemi-calcium Form VIII, now presented for examination in claims 147-166, with traverse.

Applicants respectfully request that Groups IV, V, VIII, XXXI, XXXII and XXXIII be combined for examination in this application as drawn to the various aspects of making and using atorvastatin hemi-calcium Form VIII and further that claim 188 be combined, since it is drawn to a use of the invention.

As stated in the Action, "[a] process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (1) that the process *as claimed* is not an obvious process of making the product and the process as *claimed* can be used to make other and different products, or (2) that the product *as claimed* can be made by another and materially different process." M.P.E.P. § 806.05(f) (8th ed. rev. 1, Feb. 2003) (emphasis in original). "If applicant convincingly traverses the requirement, the burden shifts to the examiner to document a viable alternative process or product, or withdraw the requirement. *Id.*

The focus of this distinctness inquiry is on the product and process as they are defined by the claims. Claims 167-184 (Groups IV, V and VIII) are directed to a process for making the atorvastatin hemi-calcium Form VIII of claim 147. No other product than atorvastatin hemi-calcium Form VIII can be made by the process claimed in claims 167-184 since the base claim 167 positively recites "conversion to the crystalline atorvastatin hemi-calcium of claim 147 or solvate thereof." Further, Applicants are unaware of a materially different process not covered by one or more of claims 167-184 that would produce Form VIII. Applicants request that the Examiner document a viable alternative process for making Form VIII or a viable alternative product of Applicants' process, which requires "conversion to the crystalline atorvasatin hemi-calcium of claim 147," or withdraw the restriction requirement between Group II (claims 147-166) and Groups IV, V and VIII (claims 167-184). MPEP § 806.05(f).

According to the Action, Groups II and Group XXXII (new claim 187) are related as product and process of use. "Where the product claims are allowable (i.e. novel and nonobvious), restriction may be required only where the process of making and the product made are distinct (MPEP § 806.05(f)); otherwise, the process of using must be joined with the process of making and product made, even if a showing of distinctness can be made

between the product and process of using (MPEP § 806.05(h)." MPEP § 806.05(i). Since the product claims are allowable and the process of making is not distinct, Applicants' claims to

use of the product must be joined with Group II. Claim 188 also is to a method of using a patentable product and must be joined with Group II.

No reasons are given in the Action for restricting Groups XXXI and XXXIII. Applicants respectfully submit that they are related to Group II as a combination of Group II and at least one pharmaceutical excipient. The excipient may be one already known in the art.

> In order to establish that combination and subcombination inventions are distinct, two-way distinctness must be demonstrated.
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> * * *
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> The inventions are distinct if it can be shown that a combination as claimed:
> (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), **and**
> (B) the subcombination can be shown to have utility either by itself or in other and different relations.
> When these factors cannot be shown, such inventions are not distinct.

MPEP § 806.05(c) (emphasis added).

Pharmaceutical compositions and dosage forms containing excipients are not novel. The novelty of claims 185 and 186 lies in the active ingredient atorvastatin hemi-calcium Form VIII. Accordingly, the combination derives its patentability from the subcombination. Consequently, there is not two-way distinctness and claims 185 and 186 also must be considered with Group II.

In addition, Applicants note that the Patent Office regularly grants patents on novel crystalline forms of chemical compounds that also contain claims to a processes for its preparation, methods of using it, and pharmaceutical compositions and dosage forms containing it, or a combination thereof, such as: U.S. Patent No. 6,060,494; 5,736,541; 5872,132; 6,080,759.

For the foregoing reasons, Applicants request withdrawl of the restriction requirement as to Groups IV, V, VIII, XXXI, XXXII and XXXIII and that all claims now pending be considered on the merits.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 147-188 are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at the number below. The undersigned may also be contacted by email at pjohnson@kenyon.com.

Respectfully Submitted,

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